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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/045,842

10/26/2001

Michel J.N. Cormier

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06/16/2006

ALZA CORPORATION

P O BOX 7210

INTELLECTUAL PROPERTY DEPARTMENT

MOUNTAIN VIEW, CA 940397210

EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT

PAPER NUMBER

1762

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

8

Office Action Summary

Application No.

10/045,842

Applicant(s)

CORMIER ET AL.

Examiner

Jennifer K. Michener

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-24, 28-35 and 47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 18-24, 28-35, and 47 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/02/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Examiner notes with appreciation Applicant's cancellation of withdrawn claims.

Double Patenting

2. *The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.*

3. Claims 18-24, 28-35, and 47 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54-64 of copending Application No. 11/034,891.

Examiner maintains the rejection.

As outlined in the previous office action, although the conflicting claims are not identical, they are not patentably distinct from each other because the Application teaches the limitations of the claims and only fails to teach the dose, solubility, and viscosity of the agent of the instant claims. However, claims in the 11/034,891 application are directed to the same active agents as the claims and specification of the instant application, which would inherently be useful in the same dosage, solubility, and viscosity as instantly claimed.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant correctly cites the MPEP and asks "does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent?", but then Applicant argues that the instant application does not describe or suggest the limitations of the patent.

It is not required for the instant claims to describe or suggest the limitations of the co-pending case. Conversely, as outlined in the MPEP and in Examiner's re-stated rejection above, the co-pending case need only describe or suggest the limitations of the instant claims. One of ordinary skill in the art regarding the co-pending case would have deemed the instant claims to be "an obvious variation" thereof as required by the MPEP. Removal of language directed to counter-ions, etc. is merely a broadening of the claim. And the additional limitations of the instant claims directed to dose, solubility, and viscosity are inherently useful for the given active agents, as outlined above.

Claim Rejections - 35 USC § 112

4. The rejections of claims 21, 23, and 29 under 35 U.S.C. 112, second paragraph, have been withdrawn based on Applicant's amendments.

Claim Rejections - 35 USC § 102

5. *The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.*

6. Claims 18-22, 28-33, and 47 are rejected under 35 U.S.C. 102(e) as being anticipated by Dalton (WO 02/07813).

Examiner maintains the rejection of the previous office action.

Claim Rejections - 35 USC § 103

7. *The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.*

Claims 23-24 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dalton.

Examiner maintains the rejection of the previous office action.

Response to Arguments

8. Applicant's arguments filed 2/2/2006 have been fully considered but they are not persuasive in regards to all claims.

Examiner has addressed the ODP rejection arguments above.

Regarding the art rejection, Applicant argues that since the present invention is entitled to the priority date of the provisional application, Dalton may not be used for prior art purposes.

Examiner notes that the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/244038, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

There does not appear to be support in the provisional document for the phrase “onto only one or more of said microprotrusions” (for reference, this phrase is present in at least claim 18). The provisional document details, throughout, the coating of the microprotrusions, not the coating of one microprotrusion.

There does not appear to be support in the provisional document for coating an agent “onto the member” (present in at least claim 18). The provisional document entails, throughout, the coating of the microprotrusions, not a member (p. 5, line 20; p. 6, lines 1 and 16; p. 7, lines 11 and 16-17; etc.). There appears to be one embodiment in which a coating can be applied to a sheet before formation of the microprotrusions, which would allow for coating that is not limited to the microprotrusions (p. 7, lines 20-25), however, this embodiment is not a method of coating a member which already has microprotrusions, as required by the claims.

There does not appear to be support in the provisional document for the phrase “analogs thereof and pharmaceutically acceptable salts thereof” (present in at least claim 23).

There does not appear to be support in the provisional document for the phrase “non-contiguous pattern” or the phrase “and an adjuvant” (present in at least claim 28 and 33, respectively).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571) 272-1424. The examiner can normally be reached on Monday through Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy H. Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "J K Michener". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Jennifer Michener
Primary Examiner
Art Unit 1762
June 12, 2006